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510(k) Premarket Notification

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Device Classification Name	Powered Laser Surgical Instrument
510(K) Number	K200525
Device Name	Medical Diode Laser Hair Removal System
Applicant	Weifang Mingliang Electronics CO., LTD No.13426, Yuqing Street, High-Tech District Weifang, CN 261000
Applicant Contact	Li Mingliang
Correspondent	Beijing Believe-Med Technology Service Co., Ltd. Rm. 912, Building#15, XiYueHui, No.5, YiHe North Rd., FangShan District Beijing, CN 102401
Correspondent Contact	Ray Wang
Regulation Number	878.4810
Classification Product Code	GEX
Date Received	03/02/2020
Decision Date	05/27/2020
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General & Plastic Surgery
510k Review Panel	General & Plastic Surgery
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

Page Last Updated: 06/01/2020

1. Gelişmiş Teknoloji: Altın kalay sinterleme teknolojisi,
2. Kulplar: Almanya/ABD lazer çubukları, 10 bar, 1000 w. Daha hızlı ve daha iyi epilasyon

için 12 bar, 1200w daha büyük güç, Gerçek acısız ve kalıcı tüy alma, bariz sonuçlarla.
Gerçek acısız ve kalıcı tüy alma, bariz sonuçlarla.

3. Hızlı tedavi: Nig spot size 10*20mm / 15*25mm / 12*38mm, frekans 1-10Hz, daha yüksek verimlilik

4. Sürekli çalışma: TEC kondansatör hava su yarı iletken soğutma sistemi, aslında su sıcaklığı sabitini kontrol edebilir

22~24°C'de, makinenin klima olmadan yaz aylarında bile 24 saat kesintisiz çalışmasını sağlayın.



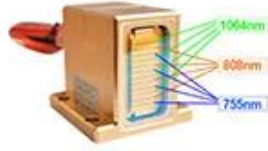
High-quality laser bars imported from Germany

1000/1200/1600ww high power

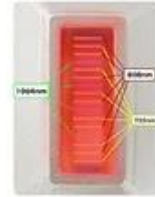
Fast hair removal



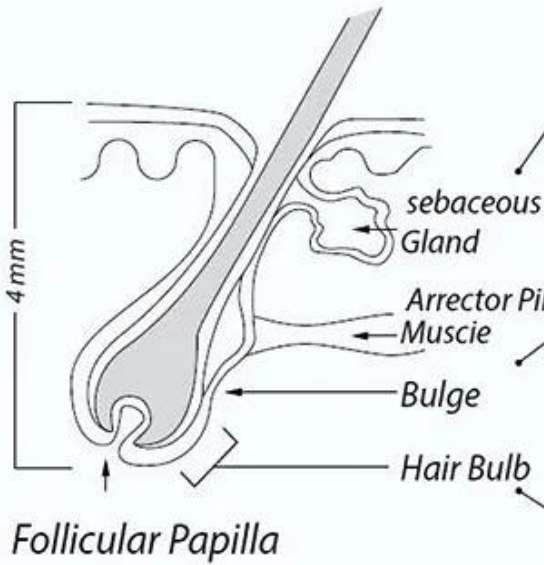
➤ 10bar
1000W



➤ 12bar
1200W



➤ 16bar
1600W



755nm

More powerful energy absorption by the melanin chromophore, making it ideal for the widest range of hair types and color
- especially light-colored and thin hair

808/810nm

Deep penetration of the hair follicle with high average power with high repetition rate for fast treatment. moderate melanin absorption level making it safe for darker skin types.
ideal for treating the arms, legs, cheeks and beard.

1064nm

low melanin absorption, focused solution for darker skin types. Offers the deepest penetration of the hair follicle, embedded hair in areas as the scalp, armpit, and pubic area.

»»Süper Soğutma etkisi:

Safir Sıcaklık-5~3°C. Tedavide ağrıyı etkili bir şekilde azaltın ve yapın

»»İtalya Su Pompası:

Lazer su çemberi için daha iyi, ısıyı uzaklaştırın, daha uzun ömür.

»»İki su filtresi:

İki gıda sınıfı deęiřim resiyonu, sirkülasyon için su kalitesini saęlayabilir



755nm



808nm



1064nm

